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UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.

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First Named Inventor or Application Identifier

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Wallace Anthony Martin,

Express Mail Label No.

EL327260974US

APPLICATION ELEMENTS

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231See MPEP Chapter 600 concerning utility patent application
contents.

1. ☒ Fee Transmittal Form (attached hereto in duplicate)
2. ☒ Specification [Total Pages 22]
(Preferred arrangement set forth below)
- Descriptive Title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 USC 113) [Total Sheets 4]
4. Oath or Declaration
- a. ☐ Newly executed (original or copy)
 - b. ☒ Unexecuted original
 - c. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional check boxes 5 and 16)
 - i. ☐ Deletion of Inventor(s)
Signed statement attached deleting
inventor(s) named in the prior application,
see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation by Reference
(useable if Box 4c is checked)
The entire disclosure of the prior application, from
which a copy of the oath or declaration is supplied
under Box 4c, is considered as being part of the
disclosure of the accompanying application and is
hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence
Submission (if applicable, all necessary)
- a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet &
document(s))
9. ☐ 37 CFR 3.73(b) Statement
(when there is an assignee) ☐ Power of Attorney
10. ☐ English Translation Document (if applicable)
11. ☐ Information Disclosure Statement
(IDS)/PTO-1449 ☐ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)

15. ☐ Other:

16. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:
Amend the specification by inserting before the first line: -- This is a ☐ Continuation ☐ Divisional
☐ Continuation-in-Part (CIP) of prior application No.: , filed . --
17. For this divisional application, please cancel original Claims of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Labelor ☒ Correspondence Address below

Name: Audley A. Ciamporocero, Jr., Esq.
Address: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003 USA

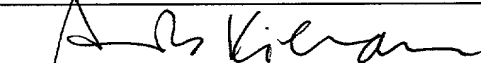
19. TELEPHONE CONTACT

Please direct all telephone calls or telefaxes to Anne B. Kiernan at:
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19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME Anne B. Kiernan Reg. No. 36566

SIGNATURE



DATE

February 1, 2000

02/01/00

jc571 U.S. PTO

jc530 U.S. PTO
09/494859

02/01/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stephen R. Beaton, George E. Himes, Daniel Tsu-Fang Wang, Donnie J. Duis and Wallace Anthony Martin

For : Customized Prescription Product Packaging and Method and System for Producing Customized Prescription Product Packaging

Express Mail Certificate

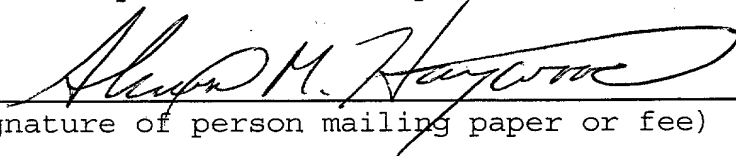
"Express Mail" mailing number: EL327260974US

Date of Deposit: February 1, 2000

I hereby certify that this complete application, including utility patent application and fee transmittal pages, specification pages, claims, informal drawings, and unexecuted Declaration and Power of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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CUSTOMIZED PRESCRIPTION PRODUCT PACKAGING AND METHOD
AND SYSTEM FOR PRODUCING CUSTOMIZED PRESCRIPTION
PRODUCT PACKAGING

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Field of the Invention

10 The present invention relates to customized prescription product packaging, and the method of producing customized prescription product packaging.

Background of the Invention

15 The packaging of contact lenses is well known in the contact lens manufacturing technology. For short-term use or single wear contact lenses, such packaging arrangements generally consist of blister packs which are employed for the storage and dispensing of the hydrophilic contact lenses by a medical practitioner or sale to a patient who wears the contact lenses. Typically, the blister packs have a plastic bowl shaped area to receive the contact lens and aqueous solution, and a cover, such as a heat-sealed lidstock which may consist of one or more polymeric or foil layers. Several blister packs may be removably attached to each other usually by the lidstock to form an array of blister packs. An example of a blister pack which is adapted to provide a sterile sealed storage environment for a disposable or single-use hydrophilic contact lens, wherein the lens is immersed in a sterile aqueous solution is described in U.S. Patent No. 4,691,820 to Martinez; which is assigned to the common assignee of the present invention, and the disclosure of which is incorporated herein by reference.

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30 Typically, one or more of the arrays of blister packs are placed in a box or carton for sale to the patient. Conventionally, the pluralities of blister packs containing the contact lenses in the sterile aqueous solutions are packaged and stored in cartons each containing a specified quantity of the blister packs; for example, 15 or 30 blister packs or other suitable quantities. Generally, the cartons are constituted of cardboard or paperboard possessing rectangular configurations and are imprinted in one or more colors with suitable identifying legends, logos, decorative indicia and/or instructions in the use of the contents, and information regarding the manufacturer, as may be required by various government regulations and/or statutes.

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40 The cartons are usually placed in large storage boxes proximate the manufacturing lines where the lenses were produced, packaged, and sterilized. The large storage boxes containing the cartons are forwarded to

distribution centers or warehouses and stocked at those locations. In the event that no further processing of the carton contents is required, upon the receipt of shipping and/or sales orders, the large storage boxes are eventually pulled from stock, the cartons containing the product, such as the blister-packaged contact lenses, are removed from the boxes, separated into individual orders which may consist of various different products, and the orders shipped to prospective customers, such as domestic or foreign distributors, physicians, optometrists or to potential users of the contact lenses.

Both the lidstock and the cartons may contain some information which is printed upon the lidstock or carton just prior to the time that the lidstock is sealed onto the blister or just prior to the time that the arrays of blister packs are placed in the cartons. The information which is added to the lidstock or the carton at this time typically is limited to the power, axis, cylinder, expiration date and lot number. All the other information and logos are usually present on the lidstock and cartons prior to packaging the contact lenses in the manufacturing line.

Summary of the Invention

This invention provides packaging for housing at least one prescription product comprising customized graphics for said packaging, said graphics are customized by the individual doctor prescribing and/or the individual patient receiving said at least one prescription product.

This invention further provides the method and system for producing customized packaging which houses at least one prescription product, wherein said packaging is customized by the individual doctor prescribing and/or said patient receiving said at least one prescription product, said method comprising the steps of:

receiving an order for at least one prescription product from said doctor or a refill order from said patient; and

printing out customized graphics specified by said doctor or said patient for said package for at least one prescription product.

This invention provides packaging and a method and system for producing customized packaging for said at least one prescription product. The benefit of this invention is to provide the doctors with the ability to customize the prescription product packages for his or her patients. The doctor can add his or her name, telephone number(s), e-mail address, website, street address, appointment information, greetings, a picture of the doctor, office, local landmark, and/or any other desired picture or information directly to the packaging materials for the prescription product. The preferred prescription product is a contact lens. This invention is particularly beneficial for doctors to provide cartons having customized graphics to new

patients who may have been fitted with trial pairs of contact lenses and must return to the doctor for a follow-up appointment. It also provides a vehicle for the doctors to advertise their practices.

Brief Description of the Drawings

Reference may now be had to the following detailed description of the preferred embodiments of the invention, taken in conjunction with the accompanying drawings; in which:

Figure 1 illustrates a perspective top and side view of a blister pack array with customized graphics;

Figure 2 illustrates a perspective top and side view of a carton with customized graphics;

Figure 3 illustrates a top view of an insert with customized graphics;

Figure 4 illustrates a top view of a label having customized graphics for a carton; and

Figure 5 is a schematic of a top view of a system for printing out labels having customized graphics for adhering to a carton.

Detailed Description of the Preferred Embodiments

The invention will be described for the preferred prescription product, a contact lens; however, any prescription product could be substituted for the contact lens. Examples of other prescription products include medications, spectacles, medical devices, or the like.

The "identification means" is a number, bar-code, two-dimensional matrix, three dimensional matrix, inductive transmitting/receiving device, or radio frequency chip, or the like. Preferably each identification means contains some unique information for every part having one. Identification means may be machine readable and/or human readable, preferably at least machine readable. A machine readable identification means preferably has information stored in a database associated with the identification means. For packaging, the information stored in the database associated with the identification means may not be present on the packaging in human-readable form. That is, the only way to know which product is in the

packaging is to access the information in the database by inputting the identification means into the database, via a bar-code reader or the like.

As shown in Figures 1, 2, and 3 the packaging having customized graphics which houses at least one contact lens can be part of any of the packaging for the contact lens. Typically, contact lens packaging comprises primary packaging and secondary packaging. The primary packaging is the packaging adjacent to the contact lens, the secondary packaging surrounds the primary packaging. There can be any number of layers of packaging for the contact lens; however, in the preferred embodiment, there is primary packaging and secondary packaging. The customized graphics can be added to the primary, and/or secondary packaging and/or it can be a package insert, typically placed within the secondary packaging. The customized graphics can be an alphanumeric message, picture, photograph, and/or the like, or combinations of the above.

The primary packaging for a contact lens is preferably a blister pack with a lidstock, but it can take any form, e.g. a glass bottle, cans, trays, pouches, e.g. form-fill-and-seal pouches, as long as it provides adequate protection for the contact lens. Figure 1 shows a blister pack array 10 having customized graphics. The blister pack array 10 consists of five blister packs 11. Each blister pack 11 consists of an individual base 12 all five of which are interconnected by a contiguous lidstock 13, which is scored so that the individual blister packs 11 can be detached from the array 10. Each base 12 preferably comprises injection-molded or thermoformed plastic incorporating a molded cavity 15 which is surrounded by an outstanding planar flange 18 about the rim of the cavity 15. A flexible cover sheet or lidstock 13 is adhered to the surface of the flange 18 so as to sealingly enclose the cavity 15 in a generally air and liquid-tight mode. Within the cavity 15 of the base portion, a contact lens (not shown) is immersed in a sterile aqueous solution (not shown). Preferably the contact lens is a hydrophilic contact lens manufactured of materials known to those of ordinary skill in the art. The customized graphics 14 shown are present on the lidstock 13 and indicate the patient to receive the contact lens in each blister pack, and which eye of the patient the contact lens should be placed in. The customized graphics 14 state on the lidstock for each blister pack: "CONTACT LENS FOR JOAN'S LEFT EYE". There may be no prescription information e.g. power for spherical contact lenses or power, cylinder, axis for toric contact lenses present on the packaging, only information indicating who the product is for, and directions for its proper use. The packaging may only be identified and tracked by the manufacturer by at least one identification means, also referred to as a product identification means, preferably a machine readable identification means present on the packaging, preferably on at least the secondary packaging, more preferably

present on both the primary packaging and secondary packaging for contact lenses. The information associated with the product identification means, such as, SKU, lot number, expiration date, can be stored in one or more databases. The information is accessible when the product identification means is inputted into a computer, which can access the database.

Presently, it is preferred that the packaging for the contact lenses comprise primary and secondary packaging. The preferred secondary packaging is a carton, but it can take any form, such as, bags, plastic wraps, envelopes, pouches, cans, boxes, bottles, or trays. The secondary packaging preferably houses multiple primary packages. The preferred secondary packaging is shown in Figure 2. Figure 2 shows a carton 20, which preferably houses multiple contact lenses each in primary packaging (such as one more of the arrays shown in Figure 1). The rectangular carton 20 preferably comprises paperboard. The carton 20 includes flat top wall panel 21 and opposing bottom wall panel (not shown) respective front panel 25 and opposing rear panel (not shown), and opposite end walls 24 (only one shown) which are sealed through an adhesive or glued construction as is known in the carton forming technology. The top wall panel 21 includes a downwardly depending front flap 26 having a centrally located latching tab 27 at a lower edge thereof which is adapted to be tucked into a cooperating latching slit (not shown) centrally formed in the front panel 25 to facilitate reclosing of the carton 20. The top wall panel 21 is adapted to be swung upwardly about a rear hinge line 28 to open the carton 20. The top wall panel 21 of the carton is shown having the customized graphics 22, 23 which consist of alphanumeric 22 and a picture 23. The alphanumeric 22 state: "CONTACT LENSES FOR JOAN SMITH PROVIDED BY DR. JONES". The picture 23 is a photograph of the doctor, Dr. Jones, who prescribed the contact lenses.

Figure 3 shows a third embodiment of the invention in which the customized graphics are added to a package insert. The package insert can be a paper or any object, e.g. a toy, a mirror, etc., which is added to the packaging. Figure 3 shows the insert 30 as a piece of paper, and the customized graphics 31 is an alphanumeric message which states: "These contact lenses are provided to Joan Smith by DR. JONES, O.D. Our office will call you in one month to schedule a follow-up. In the interim if you have any problems with these contact lenses, please call my office at 555-5555. Your eyes are important to me." The package insert paper 30 can be folded up to fit into the secondary packaging, e.g. carton. The customized graphics shown in the figures are exemplary. Any alphanumeric message, picture, or photograph selected by the doctor, or patient could be used.

Figure 4 shows a label 40. The label may be adhered to blank areas of the packaging or it may be an over-label, meaning it may be adhered to

areas of the packaging which are partially or fully labeled for distribution. The label 40 is preferably an adhesive sticker. The label 40 as shown is shaped for use on a carton similar to the carton shown in Figure 2. The label 40 consists of a top layer 47 comprising paper, polymer, (e.g. polyvinylchloride film) or metal film, preferably paper. Preferably there is an adhesive layer (not shown) coated on the back side of the top layer 47. The label 40 may be attached to a peel layer (not shown) which the top layer 47 and the adhesive layer can be peeled from before attaching the label 40 to the package. Preferably, the adhesive is a permanent adhesive, e.g. Avery Dennison adhesive LP-430 Permanent/Emulsion Acrylic with service temperature range -54 to +93 °C; Avery Dennison adhesive S-4600 Permanent/Acrylic with service temperature range -40 to +80 °C. Alternatively, the label 40 may only consist of a top layer 47 and the adhesive can be applied to the packaging before the top layer is applied to the packaging. The label 40 has multiple types of customized graphics 41, 42, and 43. The label 40 has a doctor's photograph 41, a picture of a sail boat 42, and an alphanumeric message 43 indicating that the contact lenses are "Provided by Dr. Sailor (555) 555-5555". The photograph, picture and alphanumeric message are all selected by the doctor. The doctor could specify (or a patient may select) a picture which he/she knows is well suited for a patient, e.g. a horse for a horse-lover.

As shown in Figure 4, the label may comprise additional information such as a product identification means 45, and a label identification means 46, preferably both identification means are machine-readable identification means. The product identification means 45 is used to identify the type of the contact lenses and the prescription of the contact lenses that are within the carton to which the label 40 is to be adhered to. The optional label identification means 46 can be used to identify the specific label 40, so that it can be tracked on and off the carton, so that the label is put on the correct carton, and so the product is sent to the proper recipient, either the patient or the doctor. Also, in the preferred embodiment, the label identification means is used through the customized graphics printing system for tracking the quality of the label. Alternatively, the label identification means 46 may be in a portion of the top layer 47 of the label which stays with the peel layer when the top layer 47 is removed from the peel layer, preferably just before adhering the label to the correct carton.

Also alternatively, the product identification means 45 may not be on the label and is present instead on an area of the packaging which is not covered when the label 40 is put on the packaging. If the label identification means is not present on the label the order information can be associated with the product identification means in the database and the product

identification means can be used to track the packaging after the label is adhered to the packaging. Alternatively, the label identification means can be product identification means if the label identification means is the only identification means present on the packaging.

5 The label 40 is shown having some standard graphics 44 which are not customized for either the doctor and/or the patient and may be present on the label 40 before (or added to the label 40 after) the customized graphics are printed onto the label 40, or the non-customized graphics can be printed onto the label 40 at the same time that the customized graphics are added. In short, the customized and non-customized graphics can be added to the packaging in any sequence. Non-customized information includes, e.g., identifying legends and logos pertaining to the company manufacturing and/or marketing the product, instructions pertaining to the use of the product packaged in the carton, decorative indicia the contents, directions for use, warnings about dispensing the prescription product without a prescription, and the like.

10 If the customized graphics are added to the primary package and the primary package comprises a blister pack comprising a bowl and lidstock, it is presently preferred that the customized graphics are added to the lidstock. Either the lidstock can be printed on directly to add the customized graphics or the customized graphics can be added indirectly to the lidstock by printing out a label having customized graphics and adhering the label to the lidstock. Alternatively, a label having a blank area can be adhered to the lidstock and printed on after adhering to the lidstock. The preferred methods for printing out customized graphics on labels will be described in more detail below. (The preferred method described below is presently used to print out labels for cartons, but it can be modified to print out labels for lidstock, instead.) In the embodiment shown in Figure 1, the customized graphics 10 were added to the lidstock 13 directly by printing onto the lidstock. Either an area on the lidstock can be reserved for the customized graphics or the customized graphics can cover the entire lidstock.

20 It is presently preferred that the customized graphics are added to the secondary packaging. Presently the preferred secondary packaging is a carton. The customized graphics can be added to either the outside or inside surface area of the secondary packaging. The customized graphics are preferably present on at least 5 percent of the outside surface area of the secondary packaging, more preferably at least up to 25 percent, and most preferably at least 50 percent of the outside surface area of the secondary packaging. Preferably the customized graphics comprise a background image which is present on at least 30 percent, more preferably at least 60 percent and most preferably at least 80 percent of the surface area of the secondary packaging. For a carton, preferably, at least one panel or wall

has some customized graphics, more preferably at least two panels have some customized graphics, most preferably at least three panels have some customized graphics. Alternatively or in addition to the customized graphics on the outside surface of the secondary packaging, the customized graphics can cover a portion of the inside surface area of the secondary packaging. Presently, it is preferred that the outside surfaces of the secondary packaging carry the customized graphics.

The customized graphics can be added to the secondary packaging either directly or indirectly. The secondary packaging can be printed on directly or a label may be adhered to the secondary packaging and then printed upon. For indirect printing, the customized graphics can first be printed onto a label such as the one shown in Figure 4, such as an adhesive label, which can then be adhered to the secondary packaging. The label can be small or large. The label can be used as part of the means to seal the secondary packaging, or the label can cover a portion of the outside surface area of the secondary packaging which is not near any of the sealing means, that is flaps, tear strips, insert pieces, seams, etc. of the secondary packaging. Although printing on labels first has the drawback that it requires a second step of adhering the labels to the packaging, this method is presently preferred, because not all the contact lenses ordered will be produced for doctors or patients who will want to have the customized graphics added to the packaging. The preferred method of printing out labels will be described in more detail below.

Alternatively, the customized graphics can be printed directly onto the secondary packaging. The secondary packaging may be assembled or disassembled at the time of printing with or without the primary packages within. For example, if the secondary packaging is a carton, the customized graphics may be printed on the carton as a flat carton blank or as an assembled carton which is empty. A support for an assembled empty carton which can be used during printing on the carton is disclosed in Duis et al, "METHOD AND SUPPORT FOR CARTON", US Serial No.09/217,879, filed December 21, 1998 (VTN-442) incorporated herein by reference. Alternatively, the carton may be printed on directly after the contact lens primary packages are inserted into the carton, by laser or ink jet printing. Alternatively, a label having a blank area may be added to the carton and then the customized graphics may be added to the label. If the secondary packaging is not a carton the preferred printing techniques for printing on the secondary packaging can be adapted to the secondary packaging materials used.

Alternatively, the customized graphics can be printed onto an insert which can be inserted into the secondary packaging for example in a manufacturing line before the secondary packaging is sealed.

Printing on the packaging, e.g. primary packaging, secondary packaging, and/or package insert can be by any printing method e.g. by thermal, laser, electrophotographic, ink jet, and pad printing. Some methods are better suited for certain types of packaging materials, which are known to a person of ordinary skill in the art. The preferred method for printing on a label will be described below.

For each embodiment, the method of printing the customized graphics begins with an order from a doctor for prescription contact lenses. The orders are received according to methods known in the prior art, e.g. mail, telephone, internet, fax, except that the order methods are modified so that the doctors/patients have the ability to indicate what customized graphics they would like to have on the packaging and optionally where on the packaging the customized graphics are to be placed. Preferably, there will be a large collection of pictures, photographs, and messages to select from, and each item in the collection will be coded and stored in computer memory, which will be accessible to the printing apparatus. In addition, preferably, the doctors can specify pictures, photographs or messages outside of the collection. For example, when Dr. Jones calls in his order, he can specify which cartons, if any, to print the photograph of himself which he previously provided to the manufacturer, and is stored in the computer memory which is accessible to the printing apparatus. Depending upon what packaging is to receive the customized graphics, that is, primary packaging, secondary packaging, or inserts and if the customized graphics will be added to the packaging in-line or off-line will determine how the order information will be processed. If the customized graphics are to be added to the primary packaging, then the order information will preferably be sent to a manufacturing line which has a printer for the lidstock or labels for the lidstock so that the customized graphics can be added to the primary packaging prior to placing the primary packaging in secondary packaging. If the customized graphics are to be added to the secondary packaging, the information can be sent to a contact lens manufacturing line which will either print directly onto the secondary packaging or will print onto a label for the secondary packaging either prior to or after putting the primary packages of contact lenses into the secondary packaging. The packaging which has been modified preferably will be marked with an identification means, preferably a machine readable identification means identifying to whom the order should be sent so that it can be tracked and sent to the correct doctor or patient. Alternatively, often packaging has a unique machine-readable code (e.g. product identification means) present on its exterior which is used to identify the product and other information, such as, lot number, stock keeping unit (SKU), and expiration date. This machine-readable code can have additional information assigned to it (which is preferably stored in a

database) identifying that the package has received customized graphics and to whom the product should be routed. Alternatively or additionally, the exterior of the packaging can be marked with a human-visible indicator signifying that the package has received customized graphics which may be tracked by an operator or will assist a quality check by an operator before shipping an order.

Presently, the preferred method is to manufacture the contact lenses, place the contact lenses in primary packaging, place multiple primary packages of contact lenses in secondary packaging and sterilize the lenses by the customary methods described in the prior art, and then to add the customized graphics to the secondary packaging using a label printed off-line, and preferably added off-line. Preferably, the order information for the customized graphics is sent to a customized graphics printing system which is separate from the contact lens manufacturing line. The customized graphics printing system will print out labels which will cover at least a portion of the outside surfaces of the secondary packagings, e.g. cartons. Preferably, the doctor's orders will be picked from stock in the customary method of assembling the ordered contact lenses in their customary secondary packaging. The labels produced on the customized graphics printing system will then be matched up with the secondary packaging for each doctor's order and then the labels will be adhered to the secondary packaging either in an automated method or manually. After the labels are adhered to the secondary packaging in accordance with the doctor's order, the order will be shipped directly to the doctor or patient.

In an alternative method, the customized graphics can be added in-line, that is, in the manufacturing line in which the contact lenses are produced, and placed in the primary packaging and preferably also placed in the secondary packaging. In the in-line mode, the order information will be provided to the manufacturing line which is producing the ordered contact lenses and the customized graphics will be generated right in the manufacturing line, and added to the packaging in-line. If the customized graphics are to be added to the primary package, at about the time the ordered contact lenses are placed in each of its primary packaging the customized graphics will be added to, for example, the lidstock, and then the lidstock will be heat-sealed to the bowl. If the customized graphics are to be added to the secondary packaging, the carton preferably will be printed on in the manufacturing line prior to placing the primary packagings into the carton and prior to sealing the carton. The printing can be accomplished by any of the methods listed above. The exterior of the packaging, for example the secondary packaging, will preferably have an identification means, preferably a machine-readable code, to which the information in connection

with the customized graphics will be stored for delivery to the correct recipient of the contact lenses.

In the preferred method, the graphics will be added off-line, and there will be one or more computerized databases which will track the doctors names and the selected customized graphics. As the orders for prescription products come in, as described above, and assembled in a database the order information will be searched for a request for customized graphics or for a doctor's name who has requested customized graphics on all of his/her packaging. (Alternatively, the order information will be searched for the patient's name that has requested the customized graphics). When one or more orders are found which have requested customized graphics, the customized graphics information will be sent to a customized graphics printing system. In the preferred mode labels having customized graphics will be printed by the customized graphics printing system. Afterwards, the labels will be matched up with the correct packaging, preferably cartons containing the ordered contact lenses. The preferred method of assembling or picking the ordered products is according to the method and by using the apparatus and method disclosed in Duncan et al, "Apparatus and Method for Automated Warehousing and Filling Orders for Multi-Item Inventories", U.S. Serial No. _____, filed concurrently herewith, (VTN-453), incorporated herein by reference. The picked (assembled) order will be deferred to the off-line customized graphics printing system for the application of printed labels having the customized graphics to the cartons to receive the labels in accordance with the orders.

The preferred off-line method for producing labels having customized graphics comprises a printing step, and one or more quality-checking steps. More preferably the method additionally comprises a varnishing step. Most preferably the method additionally comprises one or more cutting steps. These and other steps will be described in relationship to the preferred system for printing out labels having customized graphics as shown in Figure 5.

Figure 5 shows the presently preferred customized graphics printing system 500 comprising a printer 502, a quality check station 505, a varnish application apparatus 508, a cutting apparatus 509, a label applicator 513, and preferably shop floor controller 512. The shop floor controller 512 is a computer, or the like, tracks the labels within the printing system 500. The shop floor controller comprises memory, programs, processor, databases, and the ability to receive information, e.g., from parts of the printing system 500, and output information, and instructions, e.g., which effect the function of parts of the printing system. The operation of the shop floor controller 512 will be described below.

5 Preferably orders for contact lenses and customized graphics are received by a separate order processing system and communicated to the shop floor controller 512, preferably from a central customer order machine server (not shown). Customer orders can be received by phone, mail,
10 internet, facsimile, or by any method. Some order taking procedures are disclosed in US Patent 4,958,280, incorporated herein by reference, others are known in the art. Preferably, only the orders to receive customized graphics are communicated to shop floor controller 512. Order information includes, e.g. an order number, date of order, the person ordering, products
15 ordered, the customized graphics to be printed on the cartons, and shipping address. In the preferred system 500, the shop floor controller 512 sorts the information in the orders for the labels that are to be printed onto the web, and stores this information in a database. Fig. 6 shows a database 60 which can be used to store the sorted order information. Fig. 6 is only exemplary and more or fewer fields can be used to track the labels in the printing system 500 which would be apparent to a person of skill in the art. The database 60 includes fields for the order information such as the order number 61 (each order has an order number), and product SKU 62
20 identifying the type of product ordered, and the customized graphics 63, 64 which was specified by the doctor and/or patient for the product. Graphics field 63 specifies, e.g., background art. Graphics field 64 specifies, e.g., a message. More or fewer fields can be provided as desired. Other fields, e.g., the SKU field can indicate additional non-customized graphics to be printed onto the label. One or more of the fields in database 60 may be
25 keyed to additional databases which may provide additional information when needed, e.g. the order number may be keyed to a database having the doctor's name and address, and/or the identifying numbers in the graphics field are keyed to databases which indicate what graphics will be printed by the printer 502.

30 Preferably labels from the same order are printed adjacent to one another, and labels having similar graphics (e.g. the same background picture) are printed close to one another on the web, and a label identification means is assigned to each label. The sorted label information is communicated to the control unit 501 for the printer 502. A spool 550 of a web of label material preferably 32 cm wide is fed into a digital printer 502.
35 The label material preferably consists of a polyvinylchloride coated paper top layer with an adhesive coated back, and a removable peel layer as described in reference to Figure 4. An example of a commercially available web is a white-pigmented PVC with matte imprintable top coat on paper having an adhesive layer, such as Datacal PLV-400-FW Opaque MT/C-354 V-29 S50K-8, available from Flexicon Co. In the preferred mode the web is blank and not pre-cut or scored; however, in alternative embodiments the
40

web could be pre-cut, scored, and/or have non-customized graphics pre-printed on the web. For example, the labels could be printed individually instead of on a web, and/or the labels could also have the brand information pre-printed on them. At present, there are preferably at least 5,000 labels printed onto the web on each spool. After all the labels to be printed onto a first web have been printed onto the first web, the first spool 550 is removed from the printer 502 and replaced with a second spool 550 having a blank second web.

The digital printer 502 preferably has the ability to vary 100 % of the text and graphics for each label. The preferred printer is available from Xeikon or Indigo. The control unit 501 for the printer 502 controls the printing of the labels and instructs the printer 502, which customized graphics, and contact lens information, if any, to print on the labels as instructed by the shop floor controller 512. Each label also preferably has some label identification means, printed onto the label or on the web next to the label so that the label can be tracked. Unique information associated with the label identification means 65 is stored in database 60 in the shop floor controller 512 preferably with the location of each label on the web (preferably in fields 67, 68, 66 for row column and spool number, respectively), the customized graphics 63, 64 specified by the doctor or patient, and the product SKU 62 to receive the label. After the web moves through the printer 502 it is accumulated in an accumulator 504 before passing through a quality check station 505 which preferably uses visual inspection equipment 520, such as a spectrophotometer or densitometer to check the color density and registration of the toners, pigments or dyes. Densitometers and spectrophotometers useful for this application are available from Gretag Macbeth, such as Spectro Eye Spectrophotometer D200-11 Process Densitometer, and D19C Densitometer, and available from X-Rite, Inc., such as SP99 Multi-Angle Spectrophotometer, and 408 Color Reflection Densitometer. Presently, the densitometer is hand-held; however, a fixed densitometer may be used in the method of this invention.

Additionally, an operator can perform a subjective evaluation of the labels.

Presently, the visual inspection equipment 520 may continuously check the quality of the graphics and provide feedback to the control unit 501 which will cause the printer to automatically make adjustments, or will notify an operator if the printer cannot self-correct a printing problem. If the print quality is below a certain level, the labels in that area of the web will be rejected, which will be noted in the label control system 503 (computer comprising processing instructions and memory), and communicated to the shop floor controller 512 (computer comprising processing instructions and memory) which will schedule the rejected labels for reprinting. The rejection will be noted in field 69 of the database 60, and the shop floor controller 512

will instruct that the rejected label be reprinted. This can be accomplished by moving the fields 61, 62, 63, 64 for any rejected labels into a later record in the database with other incoming order information, while maintaining the rejected label information in the other fields for tracking purposes.

5 Preferably, an operator at the quality check station 505 will do a visual inspection of the labels on the web at set intervals, e.g. every 15 minutes. At that time an operator will scan the label identification means on the web with a handheld scanner 519 which will input at least one label identification means in the area of the web which is being inspected into a label control system 503. The handheld scanner 519 preferably is a bar code scanner. If 10 there is a problem with the labels, the operator will communicate through the handheld scanner 519, via a keypad or the like, to the label control system 503 that the labels have failed inspection, and all the labels printed since the last operator inspection are to be rejected. The rejected labels since the last inspection will be determined by the label control system 503, and 15 communicated to the shop floor controller 512. The rejection of the labels will be noted in database 60 in field 69 and eventually those labels will be reprinted.

After the quality of the print is checked the web is rewound in a 20 rewinder 506. The core of each spool 550 has an identification means, preferably a machine readable code, such as a bar code or the like, so that the shop floor controller 512 and label control system 503 can track each spool 550, and associate in the database 60 the identification means of the labels with the spool 550 on which the labels have been printed. (The label control system 503, preferably has a database similar to database 60). If 25 individual labels on the spool do not pass inspection, or if the whole spool does not pass inspection, the control system 512 will instruct the printer to reprint the labels and update the database 60 and also communicates to the label control system 503 the new location (row, column and spool) of the 30 reprinted labels. Preferably if any of the labels for a single order do not pass inspection, all the labels in an order will be reprinted on a new spool to keep all the labels for the same order together.

Next, the web on the spool will preferably be unwound on unwinder 35 507, and fed into a varnish station 508 in which the web, particularly the labels on the web, will receive a UV radiation cured varnish to improve their looks, and increase the labels' abrasion resistance. An example of a suitable varnish is INXCURE UV FLEXO P/I COATING which can be applied by, for example, a Belmark varnish applicator, which comprises anilox 40 rollers. Preferably the web is inspected after the application of the varnish to be sure that the varnish was correctly applied and to check for any other flaws or errors. The inspection can be by an operator or by visual inspection equipment (not shown) similar to the apparatus and method described

above. The inspector will preferably use a second handheld scanner 519 to input the identification means of the labels checked, and again individual labels or the entire web may be discarded if there is a problem with the varnish applicator and labels do not pass inspection. If the web is to be discarded the label control system 503 will note the identification means of the spool, and communicate this information to the shop floor controller 512, which will update the database 60, particularly field 69, and which will instruct the printer 502 to reprint all the labels on the spool. If only certain labels are to be discarded, the label control system 503 will note the label identification means of the labels that did not pass inspection, and will communicate this information to the shop floor controller 512 which will update the database 60 and which will instruct the printer 502 to reprint the labels that are to be discarded. Preferably all the labels in an order will be reprinted together on a single spool.

After inspection, the web is fed into a die cutter 509 which cuts the labels through the top layer of the web, and in a next step the top layer of the web around the labels is removed from the web, leaving the labels on the peel layer. In the preferred embodiment two separate apparatuses manufactured by Preco perform the just-described steps. In the preferred embodiment, multiple, e.g. three columns of labels are printed on the web. After cutting the labels, the web is cut widthwise into smaller reels 551, e.g. three reels, in a slitting machine 510. The reels are tracked by a machine-readable code on the core of each reel. Prior to slitting the web, the label control system 503 updates its database by assigning the labels in each column on the spool to one of three reels, which is noted in field 70, when the reels and spool are mounted upon the slitting machine. The labels are preferably printed on the web, so that labels for products in the same order are printed adjacent to one another in the same column. As shown in Fig. 6, the three products for order number 10,175 are printed in column 1 of spool 2.

Presently, labels are only printed for products which are in inventory; therefore, any reel 551 can be selected by an operator and put on the label applicator 513. When the machine readable code for the selected reel is inputted into the label control system 503, preferably via a reader (not shown) located on the label applicator 513, the products onto which labels are to be adhered are pulled from inventory and sent to the customized graphics printing system 500. In an alternative embodiment, each reel 551 can be set aside until all the cartons that are to receive the customized labels on that reel have been picked from inventory. In either embodiment, the orders for which the labels are ready for placement on the products are communicated from the shop floor controller 512 to order picking and/or assembly equipment (not shown) which picks the cartons from inventory.

Preferably, the cartons which are to receive the labels are transported to the label applicator 513 on a conveyor 514 (cutaway section shown), preferably the cartons are in the same sequence as the labels for the cartons on the reel 551. Alternatively, the cartons could be transported in assembled orders in a container or belt section (not shown) of conveyor belt 514. Each belt section can have a machine-readable code tied to the order which is within the belt section. The machine-readable code of the belt section and the related order information could be communicated to the shop floor system 512 from the equipment which assembled the orders. In any embodiment, preferably the orders are conveyed to the system 500 in the same sequence that the customized labels for the orders are present on a reel, and/or preferably the product cartons within an order are conveyed to the system 500 in the same sequence that the labels for the orders are present on the reel. Preferably, the cartons are conveyed to the label applicator on a one carton-wide conveyor 514 in exactly the sequence of the usable labels on the reel.

The cartons are conveyed to the label applicator 513. A product handler e.g. a robotic arm (not shown) may be used to pick product off the conveyor and place the product into the label applicator 513. Useful labelling equipment is commercially available. As each product receives a label it is preferably pushed or placed on a second conveyor 517 which transports the products to a final verification, packaging and shipping area (not shown). The products are preferably maintained in the same sequence, preferably with spaces between individual orders on conveyor 517.

Preferably, the label applicator 513 will only apply a label on a carton after verifying that the proper carton is present by reading the identification means on the conveyor section (if applicable) via a reader (not shown), and/or by reading the identification means on the carton via a reader (not shown), and/or by reading the label identification means via a reader (not shown). The label applicator 513 will automatically skip the labels on the reel, which are to be discarded. (The shop floor control system 512 provides the tracking information on the labels as recorded in database 60 to the label applicator 513.) The label applicator 513 also preferably comprises an inspection mechanism (not shown) which makes sure each label is in the proper position and without wrinkles prior to allowing a carton to be conveyed to shipping. If the inspection mechanism, such as a vision system, or an operator does not pass a labeled product, preferably the cartons which do not pass inspection are discarded and the method will be repeated from the beginning for those cartons, and the rest of the cartons in a single order will be set aside. If there is an error in the applicator 513 that requires an operator's attention, the operator may use the handheld scanner 519 to communicate to the label control system 503 that certain labels should be

discarded, which will be noted by database 60 and the shop floor controller 512. This step can be done at any point in the method of printing or otherwise producing the labeled product.

5 The label applicator 513 preferably continues the verifying, labeling, and inspection steps until all the labels on the reel have been put on cartons. When the reel has no more labels to apply, a signal to an operator will indicate that the reel 551 should be changed, and either the operator can place whichever reel he/she wants onto the label applicator 513, or the shop floor controller 512 will communicate to the operator the next reel 551 to put
10 on the label applicator 513, and the process of applying the labels will continue.

Before and/or after the application of the customized graphics, the packaging may have no human-readable identification of the prescription of the product and may only comprise a machine-readable identification means
15 which is used to track the product through manufacturing and shipping. The customized graphics preferably will identify who the product is for, and may not indicate any prescription information. This is particularly beneficial to prevent the product from being provided to a person who does not have a proper prescription for the product.

20 While there has been shown and described what are considered to be preferred embodiments of the invention, it will, of course, be understood that various modifications and changes in form or detail could readily be made without departing from the spirit of the invention. It is, therefore, intended that the invention be not limited to the exact form and detail herein shown and described, nor to anything less than the whole of the invention herein
25 disclosed as hereinafter claimed.

We claim:

5 1. Packaging for housing at least one prescription product comprising customized graphics on at least some surface area of said packaging, said customized graphics being selected by the individual doctor prescribing said prescription product or the patient to receive said prescription product.

10 2. The packaging of claim 1 wherein said customized graphics are specified at the time an order for said prescription product is placed.

15 3. The packaging of claim 1 wherein the customized graphics identifies the person for whom the prescription product is for.

20 4. The packaging of claim 3 wherein said packaging does not identify the prescription.

25 5. The packaging of claim 1 wherein the customized graphics identifies said doctor prescribing said prescription product.

30 6. The packaging of claim 1 wherein said prescription product is shipped from the manufacturer having said customized graphics on said packaging.

35 7. The packaging of claim 1 wherein said packaging comprises primary packaging and secondary packaging and said customized graphics are present on at least some surface area of said primary packaging or said secondary packaging.

40 8. The packaging of claim 7 wherein said customized graphics are present on at least some surface area of said primary packaging.

45 9. The packaging of claim 1 wherein said prescription product is a contact lens.

50 10. The packaging of claim 9 wherein said packaging comprises primary packaging and secondary packaging and said customized graphics are present on at least some surface area of said primary packaging.

55 11. The packaging of claim 10 wherein said primary packaging is a blister pack comprising a bowl and lidstock, wherein said customized graphics is present on said lidstock.

12. The packaging of claim 11 wherein said graphics are printed onto said lidstock.

13. The packaging of claim 11 wherein said graphics are printed onto a label which is adhered to said lidstock.

14. The packaging of claim 9 wherein said packaging comprises primary packaging and secondary packaging and said customized graphics are present on at least some surface area of said secondary packaging, said secondary packaging being a carton.

15. The packaging of claim 14 wherein said customized graphics are printed onto said carton.

16. The packaging of claim 14 wherein said graphics are printed onto a label which is adhered to said carton.

17. The packaging of claim 1 wherein said graphics comprise alphanumeric characters.

18. The packaging of claim 1 wherein said graphics comprise pictures.

19. The method of producing customized packaging which houses at least one prescription product, wherein said packaging is customized by the individual doctor prescribing and/or said patient receiving said at least one prescription product comprising the steps of:

receiving an order for at least one prescription product from said doctor or a refill order from said patient; and

printing out customized graphics specified by said doctor or said patient for said package for at least one prescription product.

20. The method of claim 19 wherein said printing step entails printing said customized graphics on primary packaging for said prescription product.

21. The method of claim 19 wherein said printing step entails printing said customized graphics on secondary packaging for said prescription product.

22. The method of claim 19 wherein said printing step entails printing said customized graphics onto a label.

23. The method of claim 22 further comprising the step of varnishing the label.

24. The method of claim 22 wherein after said printing step the method further comprises the step of adhering said label onto said packaging.

5 25. The method of claim 19 wherein the prescription product is a contact lens.

26. The method of claim 22 wherein said label has a label identification means.

10 27. The method of claim 26 wherein said packaging has a product machine readable code, and said method further comprises the step of checking said label identification means and said product machine readable code before said adhering step.

15 28. The method of claim 27 wherein said method further comprises the step of picking said prescription product in customary packaging from inventory and diverting it to a customized graphics printing system prior to said checking step.

20 29. The method of claim 19 wherein said printing step is performed by a customized graphics printing system.

25 30. A customized graphics printing system for adding customized graphics to packaging for a prescription product comprising:
a computer for receiving order information for a prescription product and for the customized graphics to be printed on the packaging for said prescription product; and
a printer for printing out said customized graphics for said packaging for said prescription product.

30 31. The system of claim 30 further comprising a varnishing application apparatus for applying varnish to said packaging.

35 32. The system of claim 30 wherein said customized graphics is printed on a label, and each label has a unique identification means.

40 33. The system of claim 32 wherein each of said labels is for a particular ordered prescription product, and said system matches up said prescription product with said label.

34. The system of claim 30, further comprising a quality check station.

35. The system of claim 33, further comprising a label applicator.

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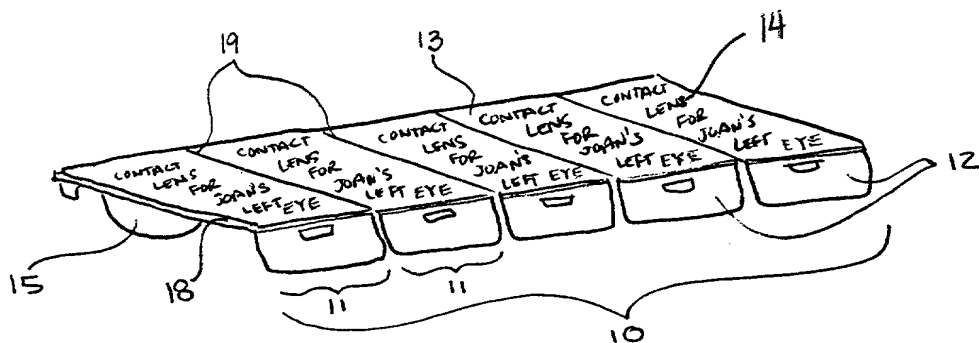


FIGURE 1

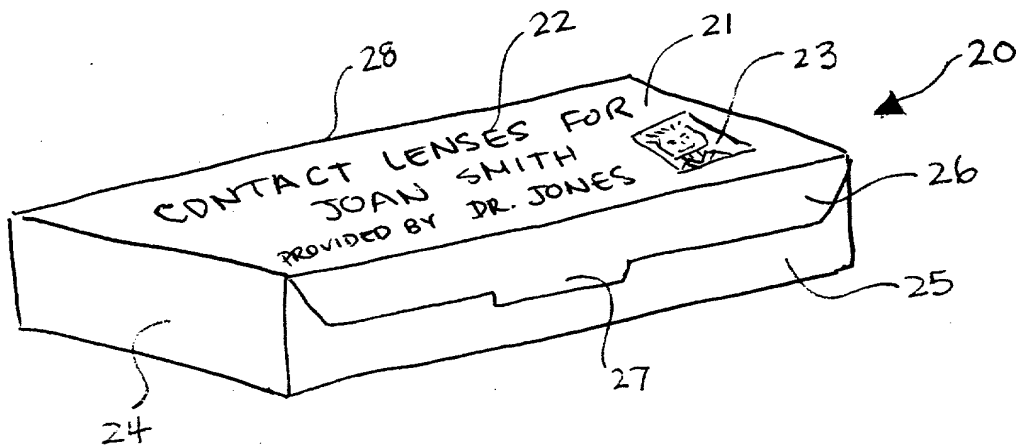


FIGURE 2

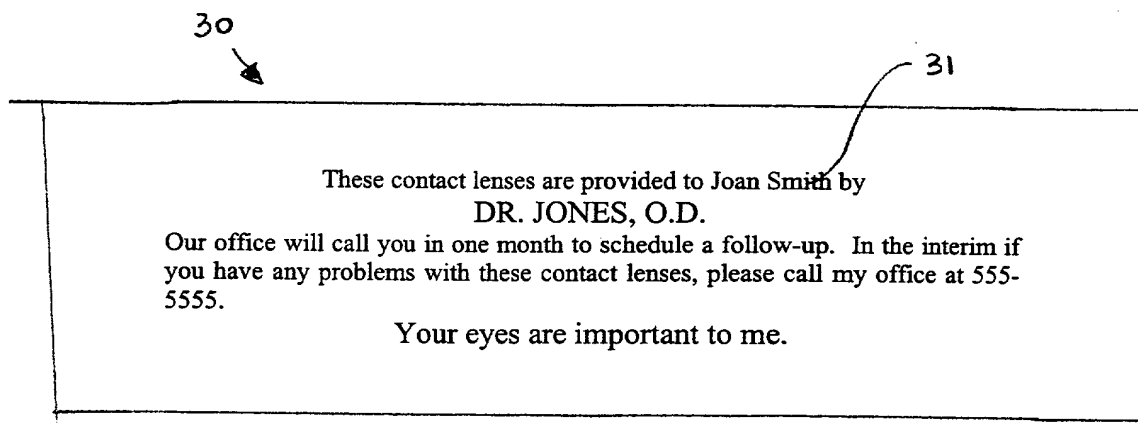


FIGURE 3

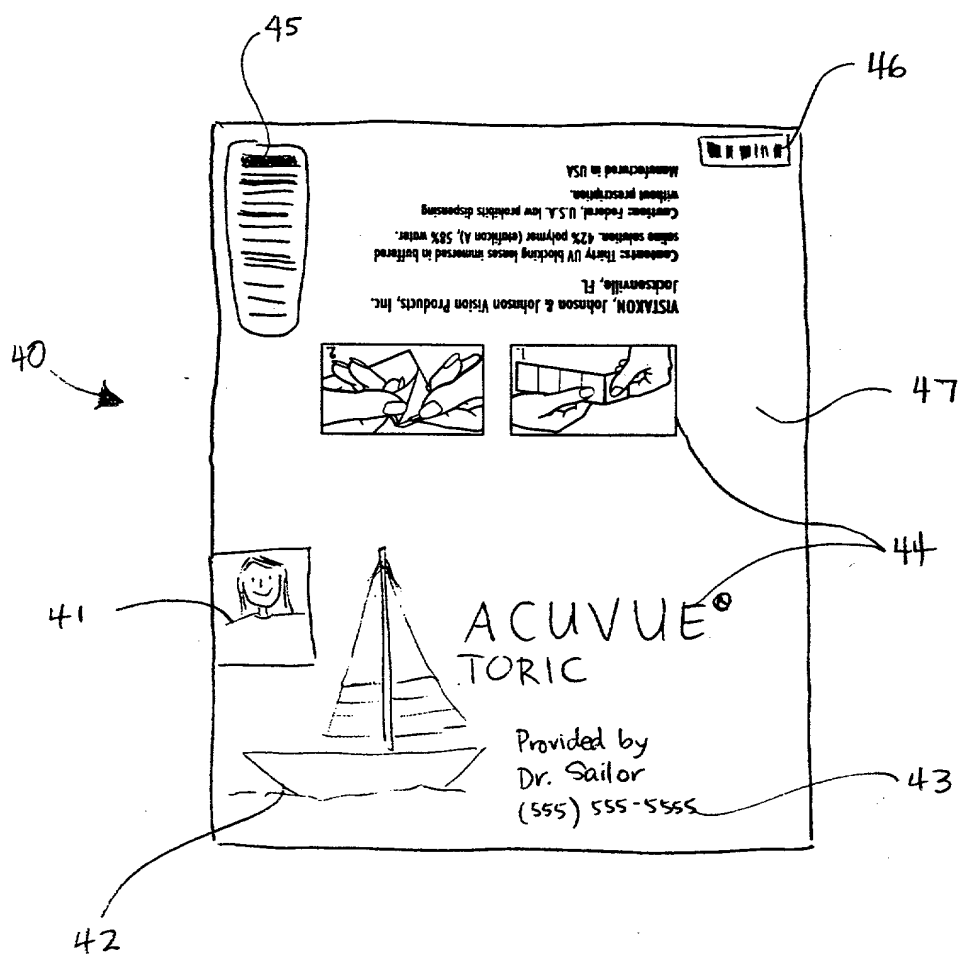


FIGURE 4

500

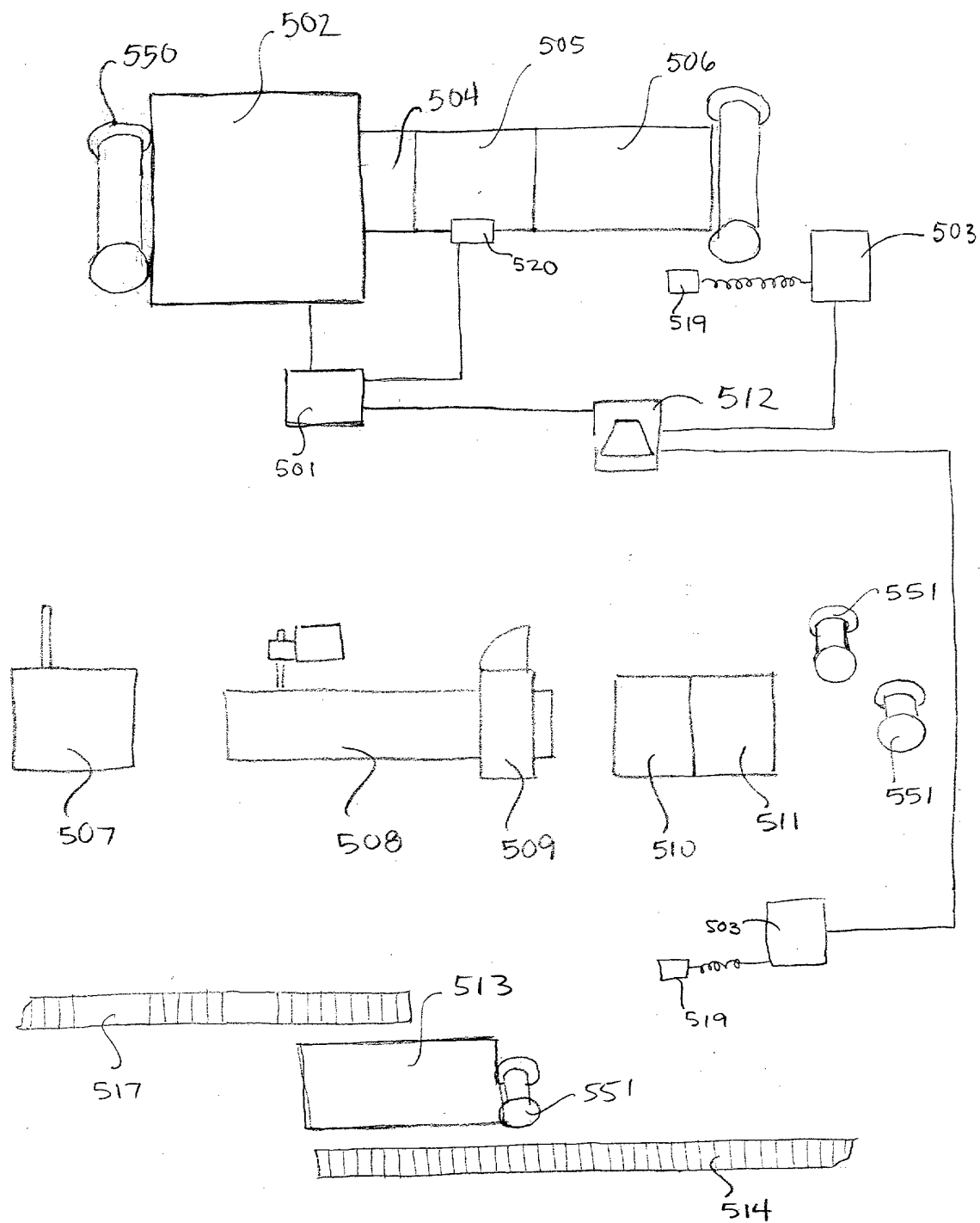


FIGURE 5

Order No.	SKU	Graphics	Graphics	Label Identification	Spool No.	Row	Column	Reject	Reel
10175	CL00525	B0781	M048	25433	2	1	1		7
10175	CL01073	B0781	M048	25434	2	2	1		7
10175	CL01073	B0781	M048	25435	2	3	1		7
11139	CL01073	B0781	M175	25436	2	4	1		7
11139	CL00091	B0489	M175	25437	2	5	1		7

60

FIGURE 6

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Customized Prescription Product Packaging and Method and System for Producing Customized Prescription Product Packaging, the specification of which

(check one) ☒ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119	
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)

(Filing Date)

(Application Number)

(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status

Application Serial No.

Filing Date

Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporzero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Michael Stark (Reg. #32,495), and Anne B. Kiernan (Reg. #36,566) One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

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I hereby declare that all statements made herein of my own
knowledge are true and that all statements made on information
and belief are believed to be true; and further that these
statements were made with the knowledge that willful false
statements and the like so made are punishable by fine or
imprisonment, or both, under Section 1001 of Title 18 of the
United States Code and that such willful false statements may
jeopardize the validity of the application or any patent issued
thereon.

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